REMARKS

Office Action

Claims 1, 2, 4-13, 15-29, 36, 40-42, and 47-54 are pending in this case. Claims 1, 2, 4-13, 15-29, 36, 40-42, and 47-54 were rejected under 35 U.S.C. § 112, first paragraph and § 102(e). Claims 10-13, 15-29, 36, 40-42, and 47-54 were rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 2, 4-13, 15-29, 36, 40-42, and 47-54 were also provisionally rejected for double patenting. Each of these rejections is addressed as follows.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 1, 2, 4-13, 15-29, 36, 40-42, and 47-54 were rejected, under 35 U.S.C. § 112, first paragraph, based on the assertion that the specification fails to provide a written description that conveys to the skilled artisan that Applicants were in possession of the claimed invention at the time of filing.

Applicants first note that *Lilly* makes clear that the written description of a genus of DNA may be achieved by a "recitation of structural features common to members of the genus." *Regents of the Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants' specification, in its description of the claimed class of acquired resistance genes and their shared, characteristic ankyrin repeat, for example, at

page 6 (lines 11-12) and page 43 (line 28) - page 44 (line 9), satisfies this standard. Moreover, Applicants have provided clear evidence (see, e.g., Bougri et al. WO 00/70069) that those skilled in the art also recognized the ankyrin motif as a structural characteristic common to members of the genus.

In further satisfaction of the written description requirement, Applicants *have* disclosed characteristic structural and functional features of the claimed compositions, as required by M.P.E.P. 2163 II A 3ii, which states:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by ...*disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics*, sufficient to show the applicant was in possession of the claimed genus.

Structural similarities between the members of the claimed gene family are echoed in functional relatedness from the dicot *Arabidopsis* to the monocots wheat, corn, and rice. Moreover, Applicants' own mutational analysis demonstrated that disruption of the ankyrin consensus, regardless of its overall size relative to the length of the proteins encoded by the claimed nucleic acids, rendered plants susceptible to disease; evidencing the ankyrin motif, which is encoded by the claimed class of acquired resistance genes, as structurally and functionally defining. Applicants have more than satisfied the standards set by the case law; the written description rejection should be withdrawn.

Claims 5 and 6 also stand rejected on the ground that the described genera "total

hundreds, if not thousands of species." To satisfy the written description requirement, however, one need only communicate to those skilled in the art that the claimed subject matter is intended to be part of the invention. Indeed, the Federal Circuit has held that the specification does not need to precisely describe all subject matter that is claimed. *In re Daniels*, 46 USPQ2d 1788 (Fed. Cir. 1998); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 227 USPQ 177 (Fed. Cir. 1985). As stated by the Federal Circuit in *Martin v. Mayer*, 3 USPQ2d 1333 (Fed. Cir. 1987):

> [T]he specification must 'convey clearly to those skilled in the art to whom it is addressed ... the information that [the inventor] has invented the specific subject matter later claimed.'

In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor "was in possession of the invention" at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). Applicants' specification meets this standard for claims 5 and 6. What is important here to the issue of written description is the fact that Applicants in their specification described and claimed cruciferous and solanaceous resistance genes. Despite the number of members of each of these groups, this description, which is beyond dispute, would be recognized by one skilled in the art. Moreover, the Office provides no basis to doubt that one skilled in the art would not immediately recognize and understand the meaning of either *Solanaceae* or *Cruciferae* or both. These bases of the written description rejection should be withdrawn.

For the record, Applicants further note that it appears to be the Office's position that Applicants have not disclosed a suitable number of resistance genes falling within the scope of the claim to support the language in the claims. The Office relies on *In re Shokal*, 113 USPQ 283 (CCPA 1957) to support its position. In particular, the Office relies on *Shokal* for the following proposition:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. 1309, 97 F.2d 623, 38 USPQ 189 In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary.
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> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

The Office, in essence, takes the position that in order to support the broad generic language found in Applicants' claim, Applicants' specification must be equally broad in naming, and in use in examples, of representative species encompassed by the claim language. The Office's reliance on *Shokal* in this situation is misplaced.

Given that Applicants' specification, as is discussed above, not only describes, in clear language, the presently claimed invention but also describes, in detail, relevant

identifying characteristics of the claimed invention, the citation to *Shokal* is not applicable to this case. Unlike Applicants' specification in this case, appellant's generic claim in *Shokal* **was not** disclosed in its specification in clear language, and appellant therefore relied on exemplary species, recited in its specification, to both illustrate and define the claimed genus. Applicants also note that "[m]ention of representative compounds encompassed by generic claim language clearly is not required by §112 or any other provision of the statute." *In re Robins,* 429 F.2d 452, 456 (C.C.P.A. 1970). Moreover, "a specification may, within the meaning of 35 U.S.C. § 112, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter v. Hiraga* 845 F.2d 993, 998 (Fed. Cir. 1988). Applicants' specification clearly conveys to the skilled person that Applicants had possession of the claimed subject matter, the written description requirement of § 112 is therefore satisfied and the rejection should be withdrawn.

Enablement

The claims stand rejected under 35 U.S.C. §112, first paragraph, as not enabled for their full scope by the specification. Specifically, the Office states that Applicants' "specification ... does not reasonably provide enablement for any nucleic acid that encodes an ankyrin-repeat-containing disease resistance protein." This rejection is again applied in error, and should be withdrawn.

The proper test of enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with the information known in the art without undue experimentation." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d. 1318 (Fed. Cir. 1985). As repeatedly stated during prosecuton of this application, at the time of filing, a skilled artisan, using no more than routine experimentation and the teachings of the present specification, could easily identify and test the function of nucleic acids falling within Applicants' current claims. Importantly, the Office has failed to provide any evidence whatsoever to refute Applicants' position, their statements, or supporting evidence provided in the Dong or Ausubel Declarations, previously made of record in this case, that detail the enabling nature of Applicants' specification.

In analyzing what constitutes undue experimentation, the MPEP (§ 2164.06) cites *In re Wands*, (8 USPQ2d 1400 (Fed Cir. 1988)):

> The test is not merely quantitative, since *a considerable amount of experimentation is permissible, if it is merely routine*, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. (emphasis added)

At the time of filing, a skilled artisan could easily identify genes falling within Applicants' claims using methods described in Applicants' specification. Such identification could easily be accomplished using standard techniques; no undue experimentation is required. On this point, Applicants' again direct the Office's attention to the Ausubel Declaration, paragraph 5, which clearly explains that "genes falling within

the scope of the present claims could routinely be identified and isolated from a variety of plant sources using nothing more than standard techniques of molecular biology." Despite Dr. Ausubel's explanation, reasoning, and scientific evidence, no evidence currently made of record in this case by the Office refutes this point.

Applicants would remind the Office that in order to make a rejection, the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. As in the previous Office Action, Applicants once again refer the Examiner to *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367, 369 (CCPA 1971). In a case in which the PTO questions the enablement of a claim, the CCPA has stated that

> a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (Emphasis added)

The MPEP (§ 2164.04) emphasizes the *Marzocchi* maxim that:

> it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning [emphasis added] which is inconsistent with the contested statement. Otherwise there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

The Office's reasoning questioning the enablement of Applicants' specification is not only unsupported by the applicable law, but it is not supported by scientific fact, scientifically-based reasoning, nor is it relevant. As explained in previous

correspondence, Applicants' statements and evidence regarding the ability to identify and, therefore, to make genes falling with the scope of Applicants' claims is in accordance with well-known scientific principles, and the Office has provided no scientifically-acceptable evidence or reason for doubting Applicants' statements, evidence, or reasoning, as supported by the Dong and Ausubel Declarations, previously made or record in this case.

Applicants also note that the MPEP (§2164.02) makes clear that

> The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims.

Applicants have provided not only scientific reasoning, but also clear evidence supporting the enablement of their specification. Moreover, the uncontested evidence made of record in this case clearly demonstrates that skilled artisans readily identified acquired resistance genes based on the structural characteristics of their sequence homology to the *Arabidopsis NPR1* gene provided by Applicants' specification and the presence of the ankyrin repeat. Given such reasoning and evidence, the Office has failed to provide adequate scientific evidence as to why "one would not expect to be able to extrapolate that one example across the entire scope of the claims."

The current Office Action also relies on *Genentech v. Novo Nordisk A/S*, but this

reliance is largely misplaced because the facts presented in this case do not parallel those presented in *Genentech*. In contrast to *Genentech,* where the specification failed to disclose a useful conjugate hGH protein or method for its cleavage, applicants' specification clearly provides the requisite starting materials.

In connection with *Ex parte Chen,* Applicants' reliance on this Board decision is to emphasize that the Patent Office, in this case, has not offered any evidence that the instantly claimed invention would require undue experimentation to practice, i.e., the Office has not carried its burden of showing a reasonable basis to doubt the enablement of the present claims.

Further, in connection with the Office's query "[i]f finding the claimed nucleic acids was so routine and straightforward, why aren't the sequences in the specification?," Applicants' note that this standard of enablement finds no basis in law. Delaying a patent filing to identify numerous genes once applicant has described and enabled an invention is inconsistent with the public policy of encouraging early disclosure and early entry of an invention into the public domain. Moreover, to restrict Applicants, in this situation, to those sequences disclosed in their application is a poor way to stimulate invention, and particularly to encourage its early disclosure. Indeed, the work described in Applicants' specification, stimulated Famodu to identify several NPR1 genes from corn, rice, and wheat using the *Arabidopsis thaliana* NPR1 gene. (See Ausubel Declaration, paragraph 5.)

In sum, as the specification enables the scope of the claims, the rejection under 35 U.S.C. § 112, first paragraph should be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 10-13, 15-39, 36, 40-42, and 47-54 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 10-12, 17, 22, 36, and 40 were rejected as indefinite in reciting the term "hybridizes." In particular the Office notes that "the hybridization conditions are not defined; thus it is unclear which nucleic acids fall within the claims." Applicants respectfully disagree.

Applicants assert that the term "hybridizes" is a clear and definite term known to a skilled artisan.

> Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph. MPEP § 2173.04

Applicants' specification, for example, at page 12 (lines 1-3), page 49 (lines 14-20), and pages 51 (line 12) - 52 (line 3), makes meaning of this claim term clear and definite. These examples are sufficient to support the assertion that the term "hybridizes" is a clearly definite term that will be understood by any skilled artisan. Further, Applicants have used the term "hybridizes" in a way that is consistent with its standard usage in this

field. A skilled worker would therefore have no trouble understanding the meaning of this term. Reconsideration on this issue is respectfully requested.

Claim 28 was deemed unclear as to whether the seed comprises the nucleic acid or vector. This rejection has been met by amending the claim to indicate that the seed is produced by the plant of claim 22.

Claim 40 was questioned as to missing the term "comprising." This rejection has been met by including that language in the claim.

Rejection under 35 U.S.C. § 102

Claims 1, 2, 4-13, 15-29, 36, 40-42 and 47-54 were rejected, under 35 U.S.C. § 102(e), as being anticipated by Ryals (U.S.P.N. 6,091,004). Applicants again note that the Ryals reference is a U.S. patent claiming subject matter that overlaps with that claimed by the present application. Thus, the reference can only be overcome by establishing priority of invention through interference proceedings. *See* MPEP (8th ed.) § 2306 and 2308.01. Applicants believe they are the first to invent the claimed subject matter. Accordingly, this 102(e) rejection should be withdrawn, and an interference should be declared to resolve this issue. Applicants further note that, as indicated in the Office Action, an interference cannot be declared until all other issues in this case have been resolved.

Double Patenting

Claims 1, 2, 4-13, 15-29, 36, 40-42 and 47-54 were provisionally rejected under the judicially created doctrine of double patenting as unpatentable over claims of copending application Serial No. 09/908,323. Applicants again note that they will file a necessary terminal disclaimer, if appropriate, once otherwise allowable subject matter has been determined.

CONCLUSION

Applicants submit that the claims are now in condition for allowance, which action is respectfully requested. If at least one of the pending claims in this application is found allowable and is claiming the same invention as at least one claim of the Ryals '004 patent, applicants respectfully request that the Examiner proceed to propose an interference.

Enclosed is a Petition to extend the period for replying to the Office Action for three months, to and including May 14, 2004, and a check for $475.00 in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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